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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/015,184	11/16/2001	Xiao-Xiong Zhou	1718-0194P	1295
2292	7590	11/28/2003	EXAMINER	
BIRCH STEWART KOLASCH & BIRCH PO BOX 747 FALLS CHURCH, VA 22040-0747			MCINTOSH III, TRAVISS C	
			ART UNIT	PAPER NUMBER
			1623	

DATE MAILED: 11/28/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

File Copy

Office Action Summary

Application No.

10/015,184

Applicant(s)

ZHOU ET AL.

Examiner

Traviss C McIntosh

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,4-8 and 10-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2,4-8 and 10-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) ✓
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 1
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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DETAILED ACTION

The Examiner of the U.S. Patent application SN 10/235,336 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to the Technology Center 1600, Art Unit 1623, attn: Examiner Traviss McIntosh.

The Amendment filed September 12, 2003 has been received, entered into the record, and carefully considered. The following information provided in the amendment affects the instant application by:

Claims 2, 4, 6, and 11-14 have been amended.

Claims 1, 3, 9, and 10 have been canceled.

Claims 17-18 have been added.

The title has been amended as indicated.

Remarks drawn to rejections of Office Action mailed April 23, 2003 include:

103(a) rejection: which has been overcome by applicant's amendments and arguments and has been withdrawn.

An action on the merits of claims 2, 4-8, and 10-18 is contained herein below.

The text of those sections of Title 35, US Code which are not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 4-8, and 10-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 2 is drawn to a method for treating HBV or HIV infections comprising administering a compound represented by the formula IId' wherein the compound comprises the group $-(CH_2)_q-$ and q is defined in the claim as 0. It is unclear why applicants have included this alkyl moiety in the compound wherein the claim thereafter removes the alkyl moiety from the structure by defining the number of units as zero. Clarity or removal of the moiety is respectfully requested. Moreover, it is unclear why applicants define p as 0, 1, or 2-20. Why is this not defined as p is 0-20? It is unclear why applicants have drafted the claim in this manner as it seems cumbersome and burdensome.

Claim 4 is drawn to a method of treating HBV or HIV comprising administering the compound of formula IId', wherein R_2 is defined as "an isoleucine or a valine derivative in said compound". In the absence of the identity of moieties intended to modify an art recognized chemical core, described structurally or by chemical name, the identity of a *derivative* would be difficult to ascertain. In the absence of said moieties, the claims containing the term "derivative" are not described sufficiently to distinctly point out that which applicant intends as the invention.

Claims 7 and 8 are drawn to a method of treating HBV or HIV comprising administering the compound of formula IId', wherein the propionyl moiety defines an L-lactic acid derivative. In the absence of the identity of moieties intended to modify an art recognized chemical core, described structurally or by chemical name, the identity of a *derivative* would be difficult to

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ascertain. In the absence of said moieties, the claims containing the term "derivative" are not described sufficiently to distinctly point out that which applicant intends as the invention.

It is unclear how the limitation set forth in claim 14, "wherein said compound is metabolized to an active metabolite which can be detected in the blood stream", is intended to further limit the claim from which it depends (claim 2). It is unclear how this step is to be practiced, and when this step is to be performed. It appears that applicants are claiming the mode of activity of the compound in a biological system, and this is not seen as a patentable limitation, but a result of the administration of the compound as set forth in claim 2.

All claims which depend from an indefinite claim are also indefinite. *Ex parte Cordova*, 10 U.S.P.Q. 2d 1949, 1952 (P.T.O. Bd. App. 1989).

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2, 4-8, and 10-18 rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-12 of U.S. Patent No. 6,458,772.

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the methods claimed in the instant application must contain new and distinguishable measures of the prior art to be patentable.

Claim 2 of the instant application is drawn to a method of treating an HBV or an HIV infection comprising administering a compound represented by formula IId'. Claims 4-8 further limit the compound of claim 2. Claim 2 of the '772 patent is drawn to a compound having the structure of formula IId', which is correlative to the structure of formula IId' in the instant application. Claims 3-8 of '772 further limit the compound correlative to claims 4-8 of the instant application. Claims 11-16 of the instant application are drawn to various amounts of active agent to be administered in the method, and to various serum levels which are to be attained to be effective in the method. Claims 17 and 18 of the instant limit the infection to HIV. Claims 11 and 12 of '772 are drawn to methods of treating viral infections (HVB or retrovirus) by administering the compound of formula IId'. It is noted that the '772 document is silent to the quantities which are to be administered and the serum levels of the compounds which are to be attained, however, it takes nothing more than routine skill in the art to administer a compound to a patient which is taught to be effective against viral infections, and determine the effective dose ranges which are to be administered. Optimization requires nothing more than routine skill in the art. The '772' document claims treating viral infections using the compound of formula IId', and the claims of the instant application are drawn to methods of treating viral infections comprising administering the same compound of formula IId'.

The claims of the instant application must contain new and distinguishable measures over the prior art methods to be patentable.

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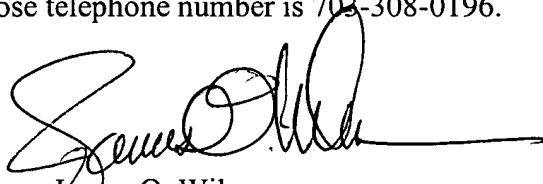
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Traviss C McIntosh whose telephone number is 703-308-9479.

The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson can be reached on 703-308-4624. The fax phone number for the organization where this application or proceeding is assigned is 703-305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



James O. Wilson
Art Unit 1623
Supervisory Patent Examiner

Traviss C. McIntosh III
November 25, 2003